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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,653	11/20/2006	David B. Weiner	UPN0022-100	2032

34136 7590 10/14/2008

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EXAMINER	
LI, BAO Q	
ART UNIT	PAPER NUMBER
1648	
MAIL DATE	DELIVERY MODE
10/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,653	WEINER ET AL.	
	Examiner	Art Unit	
	BAO LI	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 22-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 and 22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/13/07,6/23/08, 10/03/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendment filed on August 07, 2008 has been acknowledged. Claims 20-21 have been canceled. New claims 22-24 have been added. Claims 1-19 and 22-24 are pending.

Election/Restrictions

1. Applicant's election without traverse of group I with species of Ox40 in the reply filed on August 07, 2008 is acknowledged. Because new claims 22-24 are directed to the composition comprising the elected species Ox40, claims 1-19 and 22-24 in species of Ox40 are considered before the examiner.

2. Applicants are reminded to amend claims to the elected species for reflecting the examination on the merits.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-2 , 7, 15, 22-24 are rejected under 35 U.S.C. 102(a) as being anticipated by Taylor et al. (J. Leukocyte Biology Sept. 2002, Vol. 72, pp. 522-529).

5. Taylor et al. teach a method for making and using a fusion protein encoded by a nucleic acid construct comprising a nucleic acid sequence encoding the OX40 extracellular domain and

another nucleic acid sequence encoding Fc domain of human IgG fragment. The construct is a plasmid, which is prepared as a composition that can be administered into an animal model or transfected into cells for expressing an immunogenic fusion protein. Because IgG4 Fc fragment as a protein polypeptide is immunogenic, it is also considered as an immunogen (See pages 523-525). Therefore, the disclosure of the reference meets the limitation of the claims cited above. The claims are anticipated by the cited reference.

6. Claims 1, 2, 7, 8, 13, 15, 22, 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhan et al. (DNA AND CELL BIOLOGY, 2000, Vol. 19, No. 11, pp. 637-645).

7. Zhan et al. describe a DNA construct used for a transgene study in mice, wherein the DNA construct comprises two nucleic acid sequences; one of them is the DNA sequence encoding the soluble form of a surface molecule of OX40 and another one encodes CH2 and CH3 domains of Mouse IgG2a. The plasmid is transduced into mice. Because the CH2 and CH3 domains of Mouse IgG2a is a polypeptide and is immunogenic by nature as a protein, the cited reference meets the limitation of claims listed above. The claims are anticipated by the cited reference.

8. Claims 1-5, 7-11, 13-17, 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,017,735A to O'Hare et al.

9. O'Hare et al. described a method for making a fusion polypeptide comprising an amino acid sequence of Herpes virus P22 or its corresponding viral protein from HSV2, which is further optionally coupled with other viral antigen or tumor related antigen (Abstract and column 2, 10-11). The fusion polypeptide also comprises another immunological co-stimulatory sequence of OX40 as one of favorite choices (Abstract and Columns 11-12). The fusion protein is first made as a DNA construct of a plasmid or a viral vector (columns 14-16). O'Hare et al. also teach that the method for inducing an immune response can be practiced with either said DNA molecule or the fusion protein, which should be prepared in an appropriate composition implicitly (columns 9, 12 and 15). Therefore, the disclosure of the reference meets the requirement of the rejected claims. Claims 1-5, 7-11, 13-17, 22-24 are anticipated by the cited reference.

10. Claims 1-4, 7-10, 13-19, 22-24 are rejected under 35 U.S.C. 102 (e) as being anticipated by Emtage et al.(US2003/0113919A1).

11. Emtage et al. describe a method using DNA construct to induce an immune response against an immunogenic antigen, wherein the DNA construct can be made as a plasmid or a viral vector including vaccinia viral vector. The DNA construct comprises a combined nuclei acid sequence encoding an antigen and one or more nucleic acid sequence encoding co-stimulatory component(s), wherein the antigen can be any tumor/cancer associated antigen such as MAEG or an viral antigen (i.e. HPV , EBV) (paragraphs 0010-0012) and the co-immunostimulatory molecule can be OX40 (See paragraph 0066). Therefore, the disclosure of the reference meets the limitations of claims listed above; the cited reference anticipates the rejected claims.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1-19 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Emtage et al.(US2003/0113919A1) in view of Clement et al. (J. Infect. Dis. 2002, 185, pp. 165-173).

14. Emtage et al. describe a method using DNA construct to induce an immune response against an immunogenic antigen, wherein the DNA construct can be made as a plasmid or a viral vector including vaccinia viral vector. The DNA construct comprises a combined nuclei acid sequence encoding an antigen and one or more nucleic acid sequence encoding co-stimulatory component(s), wherein the antigen can be any tumor/cancer associated antigen such as MAEG or a viral antigen (i.e. HPV , EBV) (paragraphs 0010-0012), and the co-immunostimulatory molecule can be OX40 (See paragraph 0066). Emtage et al. also teach that the function of OX40 is able to stimulate more antigen presenting cells and T cells ready for participating in the ongoing immune response. But Emtage et al. do not explicitly teach using HSV2 gD as a viral antigen in the DNA construct.

15. Clement et al. teach a DNA plasmid or vaccinia viral vector encoding viral antigen of gD from HSV2 and a method comprises administering a composition of said plasmid or vector into mice to induce an immune response against a HSV infection (See abstract, Figs. 2-4).

16. Therefore, it would have been obvious to one ordinarily skilled in the art at the time of the invention was filled to be motivated by the recited references for making DNA construct by combining the methods taught by Emtage et al. and Clement et al., and using it to induce an enhanced immune response with an expected success. Because prior to the current Application was filed, the method of making and using a DNA construct encoding an antigen and OX40 was already clearly taught to be successful approach of producing an enhanced immune response to an antigen co-administered with OX40 as evidenced by Emtage et al., and the method for using HSV2 gD had also been approved to be successful for inducing an immune response effectively as evidenced by Clement et al. Therefore, obviously, placing the HSV2 gD2 in the construct is no more than placing any antigen in the construct taught by Emtage et al. for any person ordinarily skilled in the art. Hence, the claimed invention as a whole is prima facie obvious absence unexpected results.

17. Claims 1-19 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,017,735A to O'Hare et al. in view of Clement et al. (J. Infect. Dis. 2002, 185, pp. 165-173).

18. O'Hare et al. described a method for making a fusion polypeptide comprising an amino acid sequence of Herpes virus P22 or its corresponding viral protein from HSV2 that can be further optionally coupled with other viral antigen or tumor related antigen (Abstract and column 2, 10-11) and another immunological co-stimulatory sequence including OX40 (Abstract and Columns 11-12). The fusion protein is first made as a DNA construct of a plasmid or a viral vector (columns 14-16). O'Hare et al. also teach that the method of inducing an immune response can be practiced with said expression DNA vector or the fusion protein in an appropriate composition inherently (columns 9, 12 and 15). Therefore, the disclosure of the reference meets the requirement of the rejected claims. O'Hare et al. do not teach using HSV2 gD as an antigen in the construct.

19. Clement et al. teach a DNA plasmid or vaccinia viral vector encoding viral antigen of gD from HSV2 and a method comprises administering a composition of DNA plasmid or vector into mice to induce an immune response against a HSV infection (See abstract, Figs. 2-4).

20. Therefore, it would have been obvious to one ordinarily skilled in the art at the time of the invention was filled to be motivated by the recited references for making DNA construct by combining the methods taught by O'Hare et al. and Clement et al., and using it to induce an enhanced immune response with an expected success. Because prior to the current Application was filed, the method of making and using a DNA construct encoding an antigen and OX40 was already clearly taught to be successful approach of producing an enhanced immune response to an antigen co-administered with OX40 as evidenced by O'Hare et al., and the method for using HSV2 gD had also been approved to be successful for inducing an immune response effectively as evidenced by Clement et al. Therefore, obviously, placing the HSV2 gD2 in the construct is no more than placing any antigen in the construct taught by O'Hare et al. for any person ordinarily skilled in the art. Hence, the claimed invention as a whole is prima facie obvious absence unexpected results.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BAO LI whose telephone number is (571)272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao Qun Li/
Examiner, Art Unit 1648
10/10/2008